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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,860

05/25/2006

Bruce Cornish

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EXAMINER

STOUT, MICHAEL C

ART UNIT

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3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,860	Applicant(s) CORNISH ET AL.	
	Examiner MICHAEL C. STOUT	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/4/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This detailed action is in regards to United States Patent Application 10/530860 filed on 5/25/2006.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g)

prior art under 35 U.S.C. 103(a).

1. Claims 1, 2, 3, 4, 5, 6, 9, 10, 11, 12, 13, 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar et al. (US 6,339,722) in view of B.J. Thomas et al. (*"Bioimpedance Spectrometer in the Determination of Body Water Compartments: Accuracy and Clinical Significance,"* Appl. Radiation. Isotopes. VOL. 49 No. 5/6 pp. 447-455, 1998).

Regarding **claim 1** Heethaar discloses a method of determining measures of cardiac function in a patient including the steps of;

(i) generating an alternating current signal at multiple simultaneous frequencies (a current source suitable for the simultaneous generation of two low frequencies and two high frequencies, see Column 4, Lines 22-26 and Column 4, Lines 13-47) from a constant current source (current source having a constant amplitude, see Column 1 Lines 37-44) electrically isolated from the patient (Column 6, Line 66 through Column 7, Line 10).

(ii) applying the current to an outer pair of electrodes on the patient (current input electrodes 8 and 9, see Figure 1a and Column 1, Lines 5-12);

(iii) measuring a voltage signal across an inner pair of electrodes on the patient (voltage measured by electrodes 10 and 11);

(iv) demodulating the current signal and voltage signal to extract a signal (demodulator formed by 42, 43 and 44, see Column 8, Lines 40-65);

(v) determining an impedance (ΔZ , see Figure 2) at a time, where fluid distribution can then analyzed by the Cole-Cole model;

(ix) calculating measures of cardiac function in the patient from said time varying plot (Figure 2 shows the measure of the cardiac function (stroke volume) dZ/dt by a time interval, see also Column 5, Line 63 through Column 6, Line 12).

Regarding **claim 2**, Heethaar further discloses a method wherein said multiple simultaneous frequencies comprise at least three frequencies of stimulation (simultaneous generation of two low and two high frequencies, see Heethaar Column 4 Lines 23-27).

Regarding **claims 4 and 5** Heethaar further discloses a method wherein said frequencies fall within the ranges of 2-2000 kHz and 10-500kHz (the frequencies all range from 4- 2000 kHz which fall within the ranges of 2-2000 kHz and 10-500kHz, see Heethaar Column 4, Lines 25-30).

Regarding **claim 6**, further discloses a method wherein the frequency and waveform of the alternating current signal is selectable or fixed (oscillator for generating a current and have constant amplitude on at least two frequencies (fixed), see Heethaar Abstract).

Regarding **claim 9** further discloses a method further including the step of recording an ECG and correlating the ECG with the time varying plot of impedance (see Heethaar Figure 2).

Regarding **claim 10**, Heethaar further discloses a method wherein the change in the impedance value over time and the rate of change in the measured impedance

signal dZ/dt is used to determine impedance parameters to calculate cardiac output of said patient (see Heethaar Figure 2 and Column 5, Line 62 through Column 6, Line 12).

Regarding **claim 13** Heethaar further discloses a method wherein measurement steps are repeated to record at least one cardiac cycle (see Heethaar Figure 2).

Regarding **claim 14** Heethaar further discloses a method wherein measures of cardiac function are calculated using the following equation (Kubicek equation)

$$SV = \frac{\rho L^2 \left(\frac{dZ}{dt} \right)_{\max} VET}{Z_B^2}$$

See Heethaar Column 2, Lines 47-58.

Regarding **claim 16** Heethaar further discloses a method, further including the step of measuring and recording the distance between the inner electrodes (Kubicek equation where L is the distance at which the voltage measuring (inner electrodes) are placed, see Heethaar Column 2 Lines 47-58).

Heethaar fails to disclose the method of measuring bio-impedance further comprising steps (iv)-(vii): extracting signals at each of the frequencies, determining an impedance at each said frequency at a time; fitting said impedance at each frequency to a theoretical frequency dependent impedance locus; extrapolating the locus to obtain a value of impedance at zero frequency at said time.

Regarding claims 3 and 12 Heethaar further fails to disclose a method wherein said multiple simultaneous frequencies comprises at least five frequencies of stimulation. Heethaar further fails to disclose a method the theoretical frequency

dependant impedance locus is a Cole-Cole analysis.

Thomas teaches a method of measuring bio-impedance at multiple frequencies comprising extracting signals at each of the frequencies and determining an impedance at each said frequency at a time (Page 450, Column 2 First Paragraph); fitting said impedance at each frequency to a theoretical frequency dependent impedance locus (shows plotting impedance at each frequency to circular Locus, see Page 451, Column 2); extrapolating the locus to obtain a value of impedance at zero frequency at said time (the locus can be extrapolated to estimates of R_o (zero frequency impedance), see Page 541 Column 2 Last Paragraph and Page 450 Column 1 Second Paragraph);

Thomas further teaches a method wherein the theoretical frequency dependant impedance locus is a Cole-Cole analysis (see Thomas page 451 Figure 1).

Both Heethaar and Thomas teach biological impedance analysis methods. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the method as disclosed by Heethaar to include the measuring over multiple frequencies as taught by Thomas in order to improve the predictive accuracy of the measurement, see Thomas Abstract, because impedance monitoring of the heart for a cardiac function, such as stroke volume, monitors the change in fluid distribution of heart over time and a more accurate reading of the fluid distribution will result in a better estimation of the cardiac function.

Heethaar in view of Thomas further teaches the method wherein it be obvious to modify the method to further comprise said multiple simultaneous frequencies comprise at least five frequencies of stimulation, because Thomas teaches a system comprising

measurements up to 496 frequencies and Heethaar discloses simultaneous frequencies so as to limit the inconvenience for a patient to be examined, see Heethaar Column 4 Lines 23-30).

Regarding **claim 11**, Heethaar in view of Thomas further teaches the method of claim 1 wherein a time derivative of said impedance signal is mathematically obtained using the extrapolated impedance at zero frequency (Z_0) or at infinite frequency (Z_{∞}) (Heethaar discloses the time derivative of the impedance and Thomas teaches the extrapolating the impedances at Z_0 and Z_{∞} as important indicators of body fluid, see Thomas Page 450 Column 1, 2nd Paragraph, therefore it would be obvious to monitor the change in impedance overtime resulting from fluid movement by monitoring the fluid correlated values ie. Z_0 and Z_{∞}).

2. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar in view of Thomas as applied to claim 1 above, and further in view of Bernstein DP "A new stroke volume equation for thoracic electrical bio impedance," Critical Care Medicine, 1986 14: 904,909.

Heethaar in view of Thomas teaches calculating stroke volume using Sramek model but fails to teach the Bernstein model. Bernstein teaches a modified version of the Sramek model;

(see Equation [21])

which the separation of the electrodes and the height of the patient to improve accuracy by scaling the parent equation for deviation from ideal body weight.

Both Heethaar and Bernstein teach a method for calculating stroke volume.

Thus it would have been obvious to a person of ordinary skill in the art at the time of the invention to substitute the stroke volume equation taught by Heethaar for the equation taught by Bernstein in order to scale the equation for deviation from ideal body weight.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar in view of Thomas as applied to claim 1 above, and further in view of Libke et al. (5,449,000).

Heethaar in view of Thomas teaches method of claim 1 as set forth above. Heethaar fails to teach the step of measuring and recording the height, weight, sex and age of the patient.

Libke teaches a impedance measuring method including the step of measuring and recording the height, weight, sex and age of the patient, see Abstract.

Both Heethaar and Libke teach impedance methods. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify method as taught by Heethaar to include measuring and recording as taught by Libke in order to create a population prediction variable, see Libke Abstract.

4. Claims 7, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar in view of Thomas as applied to claim 1 above, and further in view of Wang (US 5,309,917).

Regarding **claims 7** Heethaar in view of Thomas teaches the method of claim 1. Heethaar fails to teach the device wherein the current signal and the voltage signal are demodulated using Fast Fourier Transform. Wang teaches a system for measuring cardiac output wherein the current signal and the voltage signal are demodulated using Fast Fourier Transform (the impedance data has been multiplied and a FFT is performed).

Because both Heethaar and Wang teach cardiac measuring systems and where there is design need a person of ordinary skill has good reason to pursue the know options within his or her technical grasp. Thus it would have been obvious to a person of ordinary skill in the art to substitute the dedicated circuit means for demodulation taught by Heethaar with the digital signal processing means of demodulating the signal using FFT methods as taught by Wang because signal processing means are well known in the art and the coding can be updated to improve the system where in a hardware based system physical components must be replaced.

Regarding **claim 8** Heethaar in view of Thomas teaches the method of claim 1, Heethaar further discloses the method wherein the demodulation of said current signal and said voltage signal provides a phase value and an amplitude value from which impedance is determined, see Figure 5 and Column 3 Lines 27- 42.

Because both Heethaar and Wang teach cardiac measuring systems and where there is design need a person of ordinary skill has good reason to pursue the know options within his or her technical grasp. Thus it would have been obvious to a person of ordinary skill in the art to substitute the dedicated circuit means for demodulation

taught by Heethaar with the digital signal processing means of demodulating the signal using FFT methods as taught by Wang because signal processing means are well known in the art and the coding can be updated to improve the system where in a hardware based system physical components must be replaced.

Regarding **claim 18** Heethaar in view of Thomas teaches the method of claim 1 as set forth above, wherein the steps of demodulating and determining an impedance at a time, comprises the steps of determine the impedance for each frequency at each time, (the instruments measure both impedance (Z) and phase angle (theta) at each frequency, see Thomas Page 450, Column 2, 1st Paragraph and Heethaar Column 8 Lines 60-62).

Heethaar fails to teach the method comprising the steps of sampling the impedance signals to obtain a sampled impedance; applying a time to frequency domain transform to said sampled signal to obtain transformed impedance signals; and filtering the transformed impedance signals and isolating each frequency to determine the impedance for each frequency at each time.

Wang teaches a method comprising the steps of sampling the impedance signals to obtain a sampled impedance (the impedance signals are sampled creating a sampled impedance by block 28, see Figure 1); applying a time to frequency domain transform to said sampled signal to obtain transformed impedance signals (FFT is applied creating transformed impedance signals, see Figure 6 fourth block and column 16, lines 38-44);

Because both Heethaar and Wang teach cardiac measuring systems and where there is design need a person of ordinary skill has good reason to pursue the know

options within his or her technical grasp. Also because signal processing means are well known in the art and the coding can be updated to improve the system where in a hardware based system physical components must be replaced. It would have been obvious to a person of ordinary skill in the art to substitute the dedicated circuit means for demodulation taught by Heethaar with the digital signal processing means of demodulating the signal using FFT methods as taught by Wang in order to achieve a system where multiple frequencies are being simultaneously measured, and impedance values are acquired for each measured frequency because it is notoriously well known in the art that a digital filter is used to isolate individual sections of a signals in the frequency spectrum in order to determine the components of the output signal resulting transfer function output of the systems combined input signal thereby determining the portion of output (impedance) of the received signal at each frequency.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar et al. (US 6,339,722) in view of B.J. Thomas et al. ("*Bioimpedance Spectrometer in the Determination of Body Water Compartments: Accuracy and Clinical Significance*," Appl. Radiation. Isotopes. Vol. 49 No. 5/6 pp. 447-455, 1998).

Heethaar et al discloses an apparatus for non-invasive measurement of cardiac function in a patient, said apparatus comprising:

a constant current source (current source, see abstract), electrically isolated from said patient (see Column 6, Lines 66-67 and Column 7, Lines 1-2), generating an

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alternating current signal at multiple simultaneous frequencies (simultaneous generation of signals, see Column 4 Lines 23-28), which is applied to an outer pair of electrodes on a patient (electrodes 8 and 9 Figure 1); an inner pair of electrodes applied to a patient for measuring a voltage signal (electrodes 10 and 11, Figure 1); signal processing means (demodulator formed by 42, 43 and 44, see Column 8, Lines 40-65) for converting said applied current signal and measured voltage signal to impedance signals at a time; and means for calculating measures of cardiac function in said patient from said impedance values (Figure 2 shows the measure of the cardiac function (stroke volume) dZ/dt by a time interval, see also Column 5, Line 63 through Column 6, Line 12), wherein the processor for determining the desired parameter (17), monitors the detected signals and presents a desired output to the indicator (18), see Column 5, Lines 29-45, the processor is capable of performing calculations and determining a cardiac function based on a time varying plot of impedance values, see Figure 2 and Equations Column 2-3 and Column 3, Lines 25-40.

Heethaar fails to disclose the system wherein signal processing means obtains impedance signals at each frequency at a time and a means for determining impedance values at a zero frequency (Z_0) and at infinite frequency (Z_{inf}) at a plurality of time intervals;

Thomas teaches a frequency impedance analyzers which are commercially available which contain signal processing means to calculate impedance for up to 496 frequencies and a means for determining impedance values at a zero frequency (Z_0) and at infinite frequency (Z_{inf}) at a plurality of time intervals; (shows plotting impedance

at each frequency to circular Locus, see Page 451, Column 2, see also Figure 1); extrapolating the locus to obtain a value of impedance at zero frequency at said time (the locus can be extrapolated to estimates of R_o , see Page 541 Column 2 Last Paragraph and Page 450 Column 1 Second Paragraph);

Both Heethaar and Thomas teach biological impedance analysis devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the simultaneous frequency apparatus as disclosed by Heethaar to include the measuring over multiple frequencies as taught by Thomas in order to improve the predictive accuracy of the measurement, see Thomas Abstract, by configuring the processor to determine the zero and infinite impedance as done by Thomas because processors are used to perform mathematical calculations to increase speed and efficiency.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar in view Thomas and further in view of Kroll et al. (US 4,890,630).

Heethaar and Thomas teach the apparatus of claim 19 as set forth above. Heethaar fails to teach the apparatus wherein said outer pair of electrodes comprise shields to protect the patient from stray current.

Kroll teaches a bio electric system wherein the electrodes comprise shields to protect the patient from stray current (the shield around the driving electrode is conductive connected to the amplifier).

Both Heethaar and Kroll teach electrode devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the apparatus as taught by Heethaar to include shields as taught by Kroll in order to minimize noise, see Column 5, Lines 10-14.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

Applicant's arguments, see Remarks, filed 6/10/2008, with respect to Claim Objections of claims 1-18 have been fully considered and are persuasive. The

objection of claims 1-18 on the grounds of insufficient antecedent basis for "the current signal" has been withdrawn.

Applicant's arguments filed 6/10/2008 have been fully considered but they are not persuasive. Regarding claim 1, the applicant argues, neither Heethaar in view of Thomas fails to teach determining impedance at each said frequency at a time, fitting the impedance at each frequency to a locus, extrapolating the locus to obtain a value of impedance at zero frequency and repeating the steps to obtain a time varying plot.

The Examiner Disagrees. Heethaar teaches applying multiple frequencies and determining an impedance a time wherein the impedance is measured over time in order to develop a time varying plot in order to determine a cardiac function by taking the time derivative of the impedance, see Column 2, Lines 47-68 and Column 3, Lines 1-43 and Figures 2, 6 and Column 8, Lines 40-65. Heethaar further teaches applying constant current at low and high frequencies to obtain impedance values of the extracellular fluid and intracellular fluid respectively for determine stroke volume and fluid distribution, using a cole-cole analysis, see Column 3, Lines 18-42 and Column 4, Line 22-34. Thomas teaches an improved method for determining body fluid distribution by measuring impedance at multiple frequencies and fitting the impedance at each frequency to a impedance locus and extrapolating the locus to obtain an impedance value at zero frequency which provide the best impedance parameters for estimating extracellular fluid, see Page 450, Paragraph 2, Figure 1 and Summary.

Regarding claim 19, the applicant argues Heethaar in view of Thomas fails to teach a means for determining the impedance value at a zero frequency and an at

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infinite frequency at a plurality of time intervals and means for calculating the cardiac function in said patient from a time varying plot of the zero frequency impedance.

The Examiner disagrees, Heethaar discloses a processor 17 for performing calculations and determining the cardiac function based on a time plot of the measure impedance and Thomas teaches devices which measure impedance for multiple frequencies, Page 450 Column 1, Paragraph 1, and where the measure impedances are best fit to a curve a plot from which the zero and infinite frequencies are calculated.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736